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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/621,802

07/16/2003

David Haines

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1612

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DELIVERY MODE

11/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/621,802	Applicant(s) HAINES ET AL.	
	Examiner ZOHREH A. FAY	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-83 and 107-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-83 and 107-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 2, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 107-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 107-113 are indefinite as to the phrase "wherein the composition comprising a caratenoid and a polyphenol comprises:" Applicant lists a group of ingredients, which some of them are neither a caratenoid nor a polyphenol.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-83 and 107-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a method of treating “a symptom of dry eye syndrome”. Such method requires treatment of unspecified disease and no evidence indicates that treatable disease was known to the applicant. Therefore, the fact pattern indicates that applicant was not in possession of the claimed method of use. In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the invention. The claims are also directed to a method of treating dry eye using “a caratenoid”, “a polyphenol” and “an omega-3 fatty acid”. The following precedent is believed to be relevant to the instant case. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, “not a mere wish or plan for obtaining the claimed chemical invention.” *Eli Lilly*, 119, F.3d at 1566. The Federal Circuit Court has adopted the standard set forth in the Patent and Trademark Office guidelines for examination of Patent applications under 35 U.S.C. 112 first “written Description” requirement (“Guidelines”), 66 Fed.Reg 1099 (Jan. 5, 2001), which state that a written description can be met by “showing that an invention is complete by disclosure of sufficient detailed, relevant identifying characteristics, “including, inter alia, functional characteristics when coupled with a known or disclosed correlation between function and structure....”*Enzo Biochem, inc. v. Gen-Probe inc.*, 296 F.3d, 316 1324-25 (Fed. Cir. 2002) (quoting guideline, 66 Fed Reg. At 1106 (emphasis added). Moreover,

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although Eli Lilly and Enzo were decided within the factual content of DNA sequences, this does not preclude extending those reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 F. sup. 2d 216, 225 (W.D.N.Y.2003).

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of suitable carotenoids, polyphenol compounds and omega-3 fatty acids. The specification describes only a limited number of such compounds. The instant claims generally recite “a carotenoid”, “a polyphenol” and “an omega-3 fatty acid”. When functional claims are drawn this broadly, they are inclusive of any carotenoid, any polyphenol and any omega-3 fatty acids. Accordingly, the instant specification fails to provide an adequate written description of “a carotenoid”, “a polyphenol” and “an omega-3 fatty acid” generally.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68, 70, 72, 73, 74, 75, 76, 77, 79, 81 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorenbein et al. (US 6,200,601).

Gorenbein et al. teach the use of a nutritional supplement of a fatty acid, DHA, a polyphenol and a carotenoids such as lutein and zeaxanthin for improving, delaying and preventing various vision disorders such as eye strain and night vision. See column 2, lines 1-67. The oral administration is taught in column 3, lines 1-4. The above reference makes clear that the claimed method of use is old and well known.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68, 70, 72, 73, 7475, 76, 77, 79, 81, 82, 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorenbein et al. (6,200,601) in view of Petrus (US 6,573,299).

Gorenbein et al. was discussed in the anticipation rejection. The primary reference differs from the claimed invention in the topical administration. Petrus teaches a composition of a caratenoid, a polyphenol, an oil, a lipoic acid, Vitamins, N-acetylcysteine, glutathione and minerals for ophthalmic use. See column 2, lines 20-35, column 6, lines 40-67 and column 14, lines 9-35. The topical administration is taught in column 14, lines 36-45. It would have been obvious to a person skilled in the art to use the composition of Corenbein et al. topically, motivated by Petrus reference, which teaches the use of the claimed components in an ophthalmic formulation being used topically. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 68, 70, 72, 73, 7475, 76, 77, 79, 81, 82, 83 are properly rejected under 35 U.S.C. 103 (a).

Applicant's arguments regarding the 112 rejection have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that the dry eye is a well known disorder. The examiner agrees with the applicant that dry eye is a well known disorder. However, the rejection was given to the phrase "a symptom of dry eye". Applicant in his remarks argues that the dry eye is associated with many symptoms, which include itching, burning, irritation, redness, blurred vision that improves with blinking, excessive tearing, increased discomfort after periods of reading, watching TV or working on a computer. The arguments have been noted. It is the examiner's position that the instant specification does not provide adequate description for using the claimed compounds or the combination of compounds for treating increased discomfort after periods of reading or watching TV, irritation, burning, itching,

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which can be caused by different sources different than dry eye. Applicant's arguments regarding the lack of adequate written description regarding the terms "caratenoids", "polyphenol" and "omega-3 fatty acids" have been noted. Applicant in his remarks argues that the specification teaches a representative number of species by chemical name, formula and function. It is the examiner's position that applicant has failed to establish a correlation between structure and function of group of compounds claimed. It is not clear that whether the function of treating dry eye is as a result of being a carotenoid, a polyphenol or an omega-3 fatty acid or something else. It is not also clear whether the compounds having the structure of polyphenols, a carotenoid or an omega-3 fatty acids or the compounds discovered in the future with such structures are capable of treating dry eye.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612